DOWD, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Kathryn J. Soehnlen, et al.,	)	
	)	CASE NO. 5:06 CV 1594
Plaintiffs,	)	
	)	
v.	)	MEMORANDUM OPINION
	)	
Aultman Hospital,	)	
	)	
Defendant.	)	
	)	

This case was removed from the Stark County Court of Common Pleas on June 30, 2006, by defendant American Red Cross.[1] Plaintiff Kathryn Soehnlen (plaintiff or Soehnlen) claims that she contracted Hepatitis C in spring 2005 while she was a patient at Aultman Hospital (defendant or Aultman) due to Aultman's negligence.[2] Plaintiff alleges that defendant was negligent by failing to: 1) properly sanitize medical equipment used to treat plaintiff, and 2) ensure that medical personnel treating plaintiff were properly sanitized.[3]

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[1] Count II of the third amended complaint alleged negligence against the American Red Cross and other defendants with respect to the albumin used in plaintiff's treatments at Aultman Hospital. The American Red Cross was terminated as a defendant subsequent to removal, as were all other defendants named in Count II. However, the Court exercises its discretion to retain jurisdiction over this case in the interest of judicial economy and fairness to the litigants.

[2] Plaintiff Kathryn Soehnlen's husband has advanced a claim in this action for loss of consortium (Count III). Defendant's motion for summary judgment pertains only to Kathryn Soehnlen's claims. However, Philip Soehnlen's claim is contingent upon the survival of Kathryn Soehnlen's claims.

[3] Plaintiff also alleged Aultman was negligent in failing to assure blood products (albumin) used to treat plaintiff were safe and free from contamination. However, plaintiff's expert has opined that her Hepatitis C infection did not result from the albumin used during her

(continued...)

Aultman has moved for summary judgment on the grounds that: 1) plaintiff has not produced expert testimony that the defendant breached any standard of care or that defendant's alleged negligence was the proximate cause of plaintiff's injury, and 2) the opinion of plaintiff's expert - that she contracted the infection at Aultman because of the timing of her positive Hepatitis C test - is flawed. (Document 121).

Defendant is granted judgment with respect to plaintiff's allegation that Aultman breached its duty to assure that the albumin used during her plamapheresis treatments was free from contamination without further discussion based upon the opinion of plaintiff's expert, Dr. Rozman, that her exposure to Hepatitis C did not result from the albumin.[4]

Plaintiff has opposed defendant's motion for summary judgment (Document 124) and defendant has replied (Document 126). Plaintiff and defendant have also both filed motions to strike various aspects of documentation filed by the other in support of their respective positions regarding the summary judgment motion.[5]

For the reasons discussed herein, defendant's motion for summary judgment is granted.

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[3](...continued)
plasmapheresis treatments at Aultman.

[4] *See* Dr. Rozman Aff., par. 9.

[5] Defendant's motion to strike (Document 125); Plaintiff's motion to strike (Document 127) and defendant's opposition (Document 128).

I. BACKGROUND

A. Facts

1. AULTMAN ADMISSION AND PLASMAPHERESIS TREATMENTS

Kathryn Soehnlen was admitted to Aultman Hospital from March 15, 2005 through March 31, 2005, and was diagnosed with Guillain-Barre Syndrome (GBS). One of the treatments she received for GBS was plasmapheresis. The process of plasmapheresis involves removal of the patient's blood, separation of the plasma from the other components of the patient's blood, and return of the other components of the patient's blood with albumin, which is a replacement plasma solution. Plaintiff received five plasmapheresis treatments during her hospitalization at Aultman, and was successfully treated for GBS.[6]

The albumin solution used to replace the patient's plasma is sealed in sterile packaging and not opened until the time of delivery to the patient.[7] All other fluids and components used in the treatments, such as saline, anticoagulant, tubing and needles, are sterile, single-use and disposable.[8] When the patient's blood is withdrawn into the plasmapheresis machine, the system is sealed and it is not exposed to the air.[9] Although breaks in the circuit are rare, the system is

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[6] Report of Dr. Davenport, p. 1.

[7] Lisa Johnstone Aff., par 4. Lisa Johnstone is the director of Aultman's dialysis unit where plainitff's plasmapheresis treatments were conducted.

[8] Lisa Johnstone Aff., par. 5. The lot numbers of the albumin, disposables, "ACD" and saline used in plaintiff's plasmapheresis treatments were recorded. Report of Dr. Davenport, p. 1.

[9] Lisa Johnstone Aff., par. 6.

under pressure so if a break in the circuit occurs, the blood comes out, but does not flow back into the patient.[10]

Aultman utilizes charting by exception, which means that deviations from the normal routine are recorded.[11] Both plaintiff's and defendant's experts agree that there is no evidence in plaintiff's Aultman admission records of any problems with the administration of plaintiff's plasmapheresis treatments or breach of any standard of care,[12] and Dr. Rozman specifically concluded from his review of the record that the nursing care plaintiff received at Aultman was unrelated to her Heptatitis C infection.[13] However, Dr. Rozman opined in his affidavit that plaintiff's Hepatitis C exposure "necessarily resulted" from "unsanitary" equipment and personnel.[14]

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[10] Report of Dr. Davenport, p. 2.

[11] Wanda Salinas Aff., Exhibit A. Wanda Salinas is a nurse at Aultman who teaches nursing personnel how to perform plasmapheresis. "I reviewed Aultman's charting of the plasmapheresis treatments given to Kathryn Soehlen [sic] and I am of the opinion that they were administered correctly and in accordance with the standard of care." *Id.*

[12] Report of Dr. Davenport; Dr. Rozman Depo., p. 28.

[13] Dr. Rozman Depo., p. 37.

[14] Dr. Rozman Aff., p. 4.

2. ALT LEVELS AT ADMISSION

At the time of her March 15, 2005, admission to Aultman, plaintiff's serum ALT levels[15] were measured to be 71. Defendant's expert states that the normal range is 9-52.[16] Defendant argues that this elevated ALT level shows that plaintiff was infected with Hepatitis C before her admission to Aultman. Plaintiff's expert states that "normal for that laboratory is 65."[17] Plaintiff's expert describes these results as "normal or near normal values" and concludes that this "mild, borderline" elevation is not evidence of pre-existing Hepatitis C, but a likely result of fat deposition in her liver.[18] For purposes of defendant's motion for summary judgment, the Court accepts the view of plaintiff's expert.

3. POSITIVE HEPATITIS C TEST

On May 2, 2005, Plainitff's blood work reflected elevated ALT levels, but a Hepatitis C antibody test was negative. Subsequent blood work through June 2005 showed increasing ALT levels. Testing conducted on July 21, 2005 was positive for the Hepatitis C antibody.[19]

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[15] ALT levels are a non-specific measure of liver inflammation. Hepatitis C, and other factors, can cause liver inflammation.

[16] Report of Dr. Post, p. 1.

[17] Dr. Rozman Depo., p. 18. Dr. Rozman is apparently referring to the laboratory which analyzed plaintiff's blood work when she was admitted to Aultman. Defendant refers to Exhibit Exhibit F to Dr. Rozman's deposition in connection with issue of "normal" ALT levels, however, it is not apparent to the Court that Exhibit F was filed with Dr. Rozman's deposition.

[18] Dr. Rozman Aff., par. 5; Report of Dr. Rozman, p. 2; Dr. Rozman Depo., p. 19.

[19] Dr. Rozman Aff., par. 5.

Defendant argues that plaintiff's negative Hepatitis C test on May 2nd was caused by the plasmapheresis treatments. Defendant's expert points out that plasmapheresis is known to remove other types of antibodies along with the patient's plasma, and may remove the Hepatitis C antibody as well, which explains defendant's theory of a pre-Aultman infection but a negative Hepatitis C antibody test on May 2nd.[20]

Dr. Rozman also concludes that plaintiff was infected with Hepatitis C despite the negative May 2nd antibody test, but for different reasons. Plaintiff's expert agrees that the process of plasmapheresis removes factors from a patient's blood when the plasma is removed,[21] but does not attribute the negative May 2nd test to the plasmapheresis process. Rather, Dr. Rozman concludes that plaintiff tested negative because it was too early to detect the Hepatitis C antibody after infection in late March or early April.[22] For purposes of defendant's motion for summary judgment, the Court accepts the view of plaintiff's expert.

4. PLAINTIFF'S FOLLOW-UP WITH DR. FRIEDMAN

After her diagnosis with Hepatitis C, plaintiff sought a second opinion on October 21, 2005, from Dr. Friedman, a practicing neurologist in Akron, Ohio, regarding the effect of treatment for Hepatitis C on her GBS. At plaintiff's request, Dr. Friedman reported his opinion to plaintiff's primary care physician, Dr. Matto. In his letter to Dr. Matto, Dr. Friedman

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[20] Report of Dr. Davenport, p. 2.

[21] Dr. Rozman Depo., pp. 38-39. Dr. Rozman acknowledges that plasmapheresis works to treat GBS because the factor impacting neuromuscular function is removed along with the patient's plasma. However, Dr. Rozman does not extend the concept of this process to the removal of the Hepatitis C antibody along with the patient's plasma, as does Dr. Davenport.

[22] Dr. Rozman Depo., p, 24.

noted that plaintiff attributed her Hepatitis C infection to the plasmapheresis treatments, but concluded as follows:

> In short, [plaintiff's] history of Guillain-Barre should not affect decision making with respect to hepatitis C. I agree with Dr. Hagan's assessment that Guillain-Barre is a monophasic illness, and should not recur with immunosuppression. Hepatitis on the other hand is a known factor in many neuropathies. Hepatitis C may in fact have predated her Guillain-Barre and possibly contributed to its development. I made [plaintiff] aware of these possibilities, and asked her to follow-up on an as needed basis."[23]

B. Parties' Experts

1. PLAINTIFF'S EXPERT - DR. ROZMAN

Dr. Rozman is a board certified gastroenterologist. He has experience in diagnosing patients with Hepatitis C, but does not specialize in liver disease. Dr. Rozman has had "two or three" patients with GBS "five to ten years ago."[24] He has observed the administration of plasmapheresis "perhaps once or twice" and has a general understanding of the process, but he does not consider himself an expert on the subject of plasmapheresis.[25] In particular, Dr. Rozman testified at his deposition that he did not know: 1) the specifics of the practice or routine of delivering plasmapheresis; 2) the specifics of safety measures taken for the protection

[23] Affidavit of Dr. Friedman and attached letter to Dr. Matto dated October 21, 2005 (Exhibit A to the affidavit). Plaintiff moved to strike Dr. Friedman's letter on the basis that it was not properly authenticated. Defendant subsequently provided an affidavit from Dr. Friedman authenticating his letter, rendering plaintiff's motion moot.

[24] Dr. Rozman Depo., pp. 25-28.

[25] Dr. Rozman Depo., pp. 28-29.

of the patient and the personnel administering plasmapheresis; or 3) the standard of care for the administration of plasmapheresis.[26]

In both his expert report and deposition testimony, plaintiff's expert, Dr. Rozman, opined that plaintiff contracted Hepatitis C during her Aultman admission. He identified plaintiff's plasmapheresis treatments as the "the most likely source" of her Hepatitis C infection.[27]

Dr. Rozman's conclusion that plaintiff contracted Hepatitis C while she was a patient at Aultman in 2005, "likely as a result of her plasmapheresis treatments," is based on his conclusion that plaintiff did not have Hepatitis C when she was admitted, the timing of the manifestation of the virus, and the access to her bloodstream provided by the plasmapheresis treatments.[28] No other information he reviewed for his report led him to that conclusion.[29]

Although Dr. Rozman concludes that plaintiff contracted Hepatitis C while a patient at Aultman, he testified at his deposition that he found no breach of any standard of care in his review of plaintiff's Aultman admission records.[30] When questioned about the source of the

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[26] Dr. Rozman Depo., pp. 29-30.

[27] Dr. Rozman Depo., pp. 30-31.

[28] "90% of all patients test positive for the Hepatitis C antibody within 90 days of exposure to the virus." Dr. Rozman Depo., pp. 16-17, 19-21, 30; Dr. Rozman Aff., par. 7. Defendant argues in its motion for summary judgment that the Court should disregard Dr. Rozman's opinion regarding the timing of plaintiff's infection because he does not have expertise in plasmapheresis or patients with Hepatitis C and because his opinion is based on unreliable methodology, citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). However, given the final analysis, the Court declines to exclude Dr. Rozman's opinions.

[29] Dr. Rozman Depo., p. 17.

[30] Dr. Rozman, Depo., pp. 17-18, 28, 37.

Hepatitis C infection or the process which conveyed the infection, Dr. Rozman testified that he could not identify the specific source or process by which the Hepatitis C virus was conveyed to plaintiff.[31]

An affidavit was prepared by Dr. Rozman subsequent to his deposition and in support of plaintiff's opposition to defendant's summary judgment motion. Dr. Rozman's affidavit does not purport to be based on new information. In his affidavit, Dr. Rozman states that a hospital has a duty to assure that medical equipment and personnel are sanitary and that if a hospital exercises "due care" and "standard hospital protocol," a patient "should not be exposed to Hepatitis C during a hospital admission." Dr. Rozman opines in his affidavit that "Ms. Soehnlen's exposure to Hepatitis C necessarily resulted from unsanitary medical equipment including the plasmapheresis treatments which she received or from unsanitary medical personnel during her admission at Aultman Hospital."[32] Defendant has moved to strike Dr. Rozman's affidavit on the grounds that it contains opinions regarding negligence and substandard care that were not present in his earlier deposition testimony.[33]

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[31] Dr. Rozman Depo., pp. 15, 30-33.

[32] Dr. Rozman Aff., p. 4.

[33] In support of its contention that Dr. Rozman's affidavit should be struck because it contradicts his earlier testimony, Aultman cites *Riley v. United Health Care of Hardin, Inc.*, 165 F.3d 28 (Table), 1998 WL 598733. In that case, plaintiff's expert conceded that it was unforeseeable that a psychiatric patient would murder his mother when released from the hospital, but later produced an affidavit that patient aggression toward his mother was one of the possible results of the patient's early release. The Sixth Circuit panel gave "no credit" to the expert's later affidavit because it contradicted the expert's earlier testimony. *Riley* at *4.

The law is well settled that a party cannot create a genuine issue of fact by filing an affidavit after a motion for summary judgment has been filed that directly contradicts earlier deposition testimony.[34] Dr. Rozman has always maintained that plaintiff contracted Hepatitis C while at Aultman, most likely from her plasmapheresis treatments, based on the timing of her positive test for Hepatitis C. Dr. Rozman testified at his deposition that, from his review of plaintiff's Aultman admission records, he could not identify any specific breach of the standard of care[35] or the specific source or process by which the infection was conveyed to plaintiff.[36]

Like his deposition testimony, Dr. Rozman's affidavit does not identify any specific breach of the standard of care or any specific source or process by which the infection occurred in plaintiff's Aultman admission records. Dr. Rozman's affidavit statement that plaintiff's

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[34] In deciding the admissibility of a post-deposition affidavit in the context of summary judgment, the Court must first determine whether the affidavit directly contradicts the prior sworn testimony of the affiant. *Aerel, S.R.L. v. PCC Airfoils, L.L.C.* 448 F.3d 899, 908 (6th Cir. 2006)("[A] district court deciding the admissibility of a post-deposition affidavit at the summary judgment stage must first determine whether the affidavit directly contradicts the non-moving party's prior sworn testimony."). "A directly contradictory affidavit should be stricken unless the party opposing summary judgment provides a persuasive justification for the contradiction." *Aerel, S.R.L.* at 908 (citing *Miller v. A.H. Robins, Co.*, 766 F.2d 1102, 1104 (7th Cir. 1985)). "[A] party cannot create a disputed issue of material fact by filing an affidavit that contradicts earlier deposition testimony.'" *Aerel, S.R.L.* at 906 (citing *Penny v. United Parcel Service*, 128 F.3d 408, 415 (6th Cir. 1997)); *Reid v. Sears, Roebuck and Co.*, 790 F.2d 453, 460 (6th Cir. 1986). If there is no direct contradiction, the affidavit should not be stricken unless the affidavit constitutes an attempt to create a sham issue of fact. *Aerel, S.R.L.* at 908 (quoting *Franks v. Nimmo*, 796 F.2d 1230, 1237 (10th Cir. 1986)).

[35] Dr. Rozman Depo., p. 18 ("I did not find any specific instances of breach of standard of care."), p. 37 ("It is my conclusion that [the plaintiff] contracted the virus while at Aultman Hospital. I cannot point to a specific breach of the standard of care by an individual that caused that to occur").

[36] Dr. Rozman Depo., p. 15.

alleged exposure to Hepatitis C at Aultman "necessarily" resulted from "unsanitary" equipment and personnel is a generalized conclusion that does not identify from plaintiff's admission records any specific breach of the standard of care or a specific source or process by which the Hepatitis C virus was conveyed to plaintiff. Accordingly, the Court does not find Dr. Rozman's affidavit to be a direct contradiction of his earlier deposition testimony.

Although Dr. Rozman has opined that plaintiff's Hepatitis C infection was likely caused by her plasmapheresis treatments and necessarily resulted from unsanitary equipment and personnel, he testified at his deposition that he did not know the specifics of the practice or routine of delivering plasmapheresis, the specifics of safety measures taken for the protection of the patient and the personnel administering plasmapheresis, or the standard of care for the administration of plasmapheresis.[37]

2. DEFENDANT'S EXPERTS - DR. DAVENPORT AND DR. POST

Defendant's expert, Dr. Davenport, is an associate professor in the Department of Pathology of the University of Michigan Medical School and the director of the fellowship program in Blood Banking and Transfusion Medicine at the University of Michigan. Dr. Davenport has specialized knowledge, skill, experience, training, and education in blood banking and transfusion medicine, and the standards of care for the performance of the plasmapheresis administered to plaintiff.

Dr. Davenport's review of plaintiff's Aultman admission records and depositions of the nurses administering the plasmapheresis treatments resulted in the following conclusions:

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[37] Dr. Rozman Depo., pp. 29-30.

> "There is no evidence of abnormal events, device alarms, or deviations from accepted medical practice in plasmapheresis. The depositions of the operators indicate that standard body substance precautions were used.
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> . . . . . .
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> While Ms. Soehnlen has hepatitis C infection, there is no evident source of the infection discernable from these records. In particular, there is no evidence that she contracted hepatitis C from plasmapheresis. Hepatitis C transmission by plasmapheresis has never been reported in the medical literature. Nor is there any reasonable mechanism that can be postulated by which she could have contracted hepatitis C infection from plasmapheresis.
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> . . . . . .
>
> All of the components of the [plasmapheresis] system that are in contact with the patient's blood are sterile, single use, and disposable. No part that could have been in contact with the patient's blood is reused. ACD and saline solutions are used for anticoagulation and priming. They are sterile and single use, and cannot transmit hepatitis. . . . Thre is no reasonable possibility that any external contamination of the plasmapheresis instrument could transmit hepatitis C. The patient's blood is entirely contained within sterile, single use, disposable plastic. Even if a break in the circuit occurs, the blood is under pressure so that blood comes out and nothing could go in. Such breaks are very rare, and when they do occur they are obvious to the operator and cause a device alarm. There is no evidence that there was any external contamination of the instrument. There is no evidence that any break in the circuit occurred. From these considerations, it is clear that Ms. Soehnlen did not contract hepatitis C from plasmapheresis. There is no evidence that any breach of the standard of care occurred in Ms. Soehnlen's plasmapheresis treatments."[38]

Defendant's expert, Dr. Post, is the Director of Hepatology and the Medical Director of Liver Transplantation at University Hospitals Case Medical Center in Cleveland, Ohio. He has specialized knowledge, skill, experience, training and education in gastroenterology and hepatology, liver disease, and specifically, the care and treatment of patients with Hepatitis C. Based on his review of plaintiff's records, Dr. Post concluded as follows:

> "The timing of the seroconversion from HV Ab negative to HCV Ab positive is consistent with recent blood exposure to Hepatitis C, which could correspond to her admission to Aultman Hospital and receiving plasmapheresis. There are several

[38] Affidavit and Report of Dr. Davenport.

difficulties in concluding that Ms. Soehnlen acquired the Hepatitis C during that admission:

1. Plasmapheresis is very unlikely to transmit Hepatitis C because the equipment used to do the procedure is sterile and the plasma or albumin is screened in such a way as to make Hepatitis C transmission extremely unlikely. My review of the medical literature did not reveal any reports of plasmapheresis implicated in transmitting Hepatitis C.
2. Ms. Soehnlen's serum ALT (measure of liver inflammation) was elevated prior to the institution of plasmapheresis.
3. The plasmapheresis treatments may have temporarily removed the HCV Ab from Ms. Soehnlen's blood only to have it return in July, 2005.
4. Ms. Soehnlen had a remote cholecystectomy at which time she may have been exposed to Hepatitis C.
5. We have no liver biopsy to help time the exposure to Hepatitis C.
6. There was no previous HCV Ab or PCR testing done which could confirm or refute the presence of Hepatitis C prior to Ms. Soehnlen's admission to Aultman Hospital.
7. Ms. Soehnlen's chronic fatigue and RUQ pain are consistent with previous Hepatitis C infection.
8. Serum transaminases (ALT and AST) are known to rise and fall in patients with Hepatitis C; an elevation of AST and ALT does not necessarily suggest an acquisition event.

In conclusion, although it is possible that Ms. Soehnlen acquired Hepatitis C sometime in March of 2005, I cannot be certain as to the timing of the acquisition, which may have been many years before."[39]

II. LAW

A. Summary Judgment Standard

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. When considering a motion for summary judgment, "the inferences to be drawn from the underlying facts contained in [affidavits, pleadings, depositions, answers to interrogatories, and admissions]

[39] Affidavit and Report of Dr. Post.

must be viewed in the light most favorable to the party opposing the motion." *U.S. v. Diebold, Inc.*, 369 U.S. 654, 655 (1962). However, the adverse party "may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

Initially, the moving party has the burden of establishing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1477, 1479 (6th Cir. 1989). "[T]he moving party need not support its motion with evidence disproving the non-moving party's claim, but need only show that 'there is an absence of evidence to support the non-moving party's case.'" *Mich. Prot. & Advocacy Serv., Inc. v. Babin*, 18 F.3d 337, 341 (6th Cir. 1994)(quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)).

When this burden is met, the Rule requires the nonmoving party who has the burden of proof at trial to oppose a proper summary judgment motion "by any of the kinds of evidentiary material listed in Rule 56(c), except the mere pleadings themselves[.]" *Celotex Corp. v. Catrett*, at 324. General averments or conclusory allegations of an affidavit do not create specific fact disputes for summary judgment purposes. *See Lujan v. National Wildlife Federation*, 497 U.S. 871, 888-89 (1990). Nor may a party "create a factual issue by filing an affidavit, after a motion for summary judgment has been made, which contradicts . . . earlier deposition testimony." *Reid v. Sears Roebuck & Co.*, 790 F.2d 453, 460 (6th Cir. 1986) (citing *Biechell v. Cedar Point, Inc.*, 747 F.2d 209, 215 (6th Cir. 1984)); *but see Baer v. Chase*, 392 F.3d 609, 623-26 (3d Cir. 2004) (noting that a so-called "sham" affidavit need not be disregarded if there is "independent

evidence in the record to bolster [the] otherwise questionable affidavit"). Further, "'[t]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff.'" *Street* at 1477 (quoting *Anderson v. Liberty Lobby*, 477 U.S. at 252).

In sum, "[t]he inquiry performed is the threshold inquiry of determining whether there is the need for a trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby*, 477 U.S. at 250. Put another way, this Court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* At 251-52. *See also Wexler v. White's Fine Furniture, Inc.*, 317 F.3d 564, 578 (6th Cir. 2003) ("[t]he conflicting proof and the inferences that can be drawn therefrom raise genuine issues of material fact that preclude the grant of summary judgment").

B. Medical Negligence

Plaintiffs alleging medical negligence under Ohio law must establish through expert testimony the relevant standard of care, deviation from the standard, and injury proximately caused by the deviation. *Berdyck v. Shinde*, 66 Ohio St. 3d 573, 578-582, 613 N.E.2d 1014, 1020-1023 (1993)(citing *Bruni v. Tatsumi*, 46 Ohio St. 2d 127, 130-135, 346 N.E.2d 673, 676 (1976)). Standard of care is determined by what a hospital or health care provider of ordinary skill, care and diligence would do or not do under similar conditions and circumstances. *Bruni* at Syllabus No. 1.

Expert testimony is ordinarily required to establish the requisite standard of care. *Hoffman v. Davidson*, 31 Ohio St. 3d 60, 62, 508 N.E.2d 958, 960-961 (1987). However, in negligence actions regarding conduct within the common knowledge and experience of jurors, such as patients who fall from their hospital bed while unattended, expert testimony is not required. *Berdyck* at 581.

In this case, plaintiff alleges that Aultman was negligent by failing to properly sanitize medical equipment and personnel involved in her treatment and that this negligence caused her to become infected with Hepatitis C.[40] The manner of transmission of the Hepatitis C virus, what constitutes "proper sanitization and disinfection procedures" in a hospital, the standard of care for plasmapheresis administration and the maintenance of sanitary conditions for the delivery of plasmapheresis are beyond the knowledge and experience possessed by lay persons. Accordingly, expert testimony is required to establish the elements of plaintiff's medical negligence claim.

C. *Res Ipsa Loquitur*

Res ipsa loquitur is not a substantive rule of law. It is an evidentiary rule that permits, but does not require, an inference of negligence to be drawn when logical premises for the inference are demonstrated. *Morgan v. Children's Hospital*, 18 Ohio St. 3d 185,

[40] Plaintiff contends that it is "common sense" and a concept "which can easily be understood by lay persons" that a patient should not be exposed to Hepatitis C if "due care and standard hospital protocol are followed" and that "a patient admitted to a hospital should not be exposed to a communicable blood disease if proper sanitization and disinfection procedures are employed by hospital personnel." Document 124, pp. 10 and 24.

187-188, 480 N.E.2d 464, 465-466 (1985)(citing *Jennings Buick, Inc. v. Cincinnati*, 63 Ohio St. 2d 167, 169-170, 406 N.E.2d 1385 (1980)). The doctrine of *res ipsa loquitur* does not alter the nature of a plaintiff's claim in a negligence action - it is only a method of proving negligence through the use of circumstantial evidence. *Jennings Buick* at 170.

To warrant the application of *res ipsa loquitur*, plaintiff must show that:

1) the instrumentality causing the injury was under the exclusive control of the defendant, and

2) the injury occurred under such circumstances that in the ordinary course of events it would not have occurred if ordinary care had been observed. *Hake v. George Wiedermann Brewing Co.*, 23 Ohio St. 2d 65, 66-67, 262 N.E.2d 703, 705-706 (1970).

When applicable, the doctrine permits an inference of negligence and plaintiff is not required to establish specific evidence of negligent acts. However, it is first necessary to establish ordinary care and that the injury would not have occurred if ordinary care had been observed. *Schafer v. Wells*, 171 Ohio St. 506, 172 N.E.2d 708 (1961)(Syllabus No. 3).

When applicable in medical negligence cases, *res ipsa loquitur* permits an inference to be drawn of a deviation from the standard of care. However, plaintiff must first produce expert evidence to establish the applicable standard of care and that the injury would not have occurred in the ordinary course of events if the standard of care had been observed. *Cook v. Toledo Hospital*, 169 Ohio App. 3d 180, 192, 862 N.E.2d 181, 190-191 (Ohio App. 6 Dist. 2006).

It is plaintiff's burden to establish applicability of the doctrine of *res ipsa loquitur*. *Jennings Buick* at 171. Whether plaintiff has made this showing is a question of law.

Hake at 67. The doctrine is not applicable "where the facts are such that an inference that the accident was due to a cause other than defendant's negligence could be drawn as reasonably as that it was due to [defendant's] negligence. Where all of the facts connected with the accident fail to point to the negligence of the defendant as the proximate cause of the injury, but show a state of affairs from which an inference could as reasonably be drawn that the accident was due to a cause or causes other than the negligent act of defendant . . . ." *Jennings Buick* at 172 (quoting *Loomis v. Toledo Railways & Light Co.*, 107 Ohio St. 161, 169-170, 140 N.E.2d 639, 642 (1923)(internal quotations and citations omitted)).

III. ANALYSIS

When moving for summary judgment, defendant need not disprove plaintiff's claims and show it did not proximately cause her to become infected with Hepatitis C. Rather, Aultman need only show there is an absence of evidence to support plaintiff's case.

There is considerable evidence in the record from which the trier of fact could reasonably conclude that plaintiff was infected with Hepatitis C before she was admitted to Aultman. However, the Court assumes for the purpose of this analysis that plaintiff contracted Hepatitis C during her Aultman admission.

In order to prove medical negligence, plaintiff must prove three elements through expert testimony: 1) the relevant standard of care; 2) defendant's breach of that standard of care; and 3) that defendant's breach was the proximate cause of plaintiff's Hepatitis C infection. In support of its motion for summary judgment, Aultman produced expert evidence that it did not

breach the standard of care in plaintiff's plasmapheresis treatments and did not cause plaintiff to contract Hepatitis C from her plasmapheresis treatments.[41]

Defendant has met its initial burden by offering the opinion of a medical expert showing that there is an absence of evidence to support plaintiff's medical negligence claim and that it is entitled to judgement as a matter of law. In opposing Aultman's motion, plaintiff must set out specific facts showing there are genuine issues for trial.

Plaintiff concedes that she cannot identify the specific negligent act which was the proximate cause of her Hepatitis C infection. Dr. Rozman testified at his deposition that his examination of plaintiff's Aultman admission records revealed no breach of any standard of care, and no specific source or process by which the infection was conveyed to plaintiff. However, Dr. Rozman concludes that plaintiff's Hepatitis C infection "necessarily resulted" from unsanitary medical equipment or personnel during her Aultman admission, including her plasmapheresis treatments. Plaintiff argues that because she cannot point to the specific negligent act which caused her Hepatitis C infection, the doctrine of *res ipsa loquitur* should be applied to infer Aultman's negligence and defeat defendant's summary judgment motion.

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[41] *See* Report of Dr. Davenport. "There is no evidence that any breach of the standard of care occurred in Ms. Soehnlen's plasmapheresis treatments. . . . In summary, I find no fault in the medical care that Ms. Soehnlen received at Aultman Hospital and cannot ascribe her Hepatitis C infection to her plasmapheresis treatment."

Aultman has also offered expert evidence in support of its motion that plaintiff was infected with Hepatitis C before her Aultman admission. *See* Reports of Dr. Davenport and Dr. Post. However, as noted earlier, for the purpose of this analysis, the Court accepts as true the opinion of plaintiff's expert that Soehnlen was not infected with Hepatitis C before her Aultman admission.

It is plaintiff's burden to establish the applicability of *res ipsa loquitur*. To do so, plaintiff must show that the instrumentality causing the infection was under the exclusive control of the defendant and that Hepatitis C infection would not ordinarily have occurred if Aultman had not breached the standard of care.

Exclusive Control: Plaintiff argues that the instrumentality causing her infection was the equipment and personnel used to treat plaintiff, over which defendant exercised exclusive control. Plaintiff's expert opines that plaintiff's Hepatitis C infection "necessarily resulted" from unsanitary equipment, including plasmapheresis equipment, and unsanitary personnel involved in Soehnlen's treatments during her Aultman admission. However, the instrumentality causing plaintiff's infection was body fluids infected with Hepatitis C. There is no evidence that Hepatitis C was present on the plasmapheresis equipment or personnel administering plaintiff's plasmapheresis treatments. Further, Aultman does not exercise exclusive control over every source of Hepatitis C virus that may be present in the hospital. Hepatitis C is "the most common chronic blood borne viral infection in the United States."[42] Plaintiff's expert, Dr. Rozman, agreed at his deposition that infected individuals may be unaware they are infected and show no clinical symptoms for long periods of time.[43] According to the Center for Disease Control, 80% of persons infected with Hepatitis C have no signs or symptoms and the consequences of chronic

[42] *See* www.cdc.gov.ncidod/diseases/hepatitis/c/plan/HCV_infection.htm. About 2.7 million people are chronically infected. *Id.* (Survey conducted in the early 1990's).

[43] Dr. Rozman Depo., pp. 21-22.

liver disease from Hepatitis C do not become apparent for 10-20 years after infection.[44] Aultman does not exercise exclusive control over every source of Hepatitis C virus that may be present in the hospital at any given time - Aultman is a public place where infected individuals most certainly enter and over which Aultman has no control.

Aultman also does not have exclusive control over the process for transmission of Hepatitis C. Dr. Rozman agreed at his deposition that 10-50 percent of infected individuals do not know how they contracted Hepatitis C.[45] According to the Center for Disease Control, about 10 percent of infected individuals "have no recognized source for their infection."[46] If the virus can be transmitted in unknown and unrecognized ways from unknown sources, then although Aultman may exercise exclusive control over the equipment and personnel used to treat plaintiff, Aultman's equipment and personnel are not the exclusive process in the hospital by which the virus may be conveyed. Aultman does not have exclusive control over unrecognized and unknown sources and processes by which Hepatitis C is conveyed that may be present in the hospital at any given time.

Infection Would Not Have Occurred if Standard of Care Observed: Even assuming that Aultman exercised exclusive control over the instrumentality causing plaintiff's Hepatitis C infection, plaintiff must establish through expert testimony the applicable standard of care and that the infection would ordinarily not have occurred if the standard of care had been observed.

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[44] *See* www.cdc.gov.ncidod/diseases/hepatitis/c/fact.htm, and www.cdc.gov.ncidod/diseases/hepatitis/c/plan/HCV_infection.htm.

[45] Dr. Rozman Depo., pp. 21-22.

[46] *See* www.cdc.gov.ncidod/diseases/hepatitis/c/plan/HCV_infection.htm.

Plaintiff has not established the relevant standard of care - i.e., what hospitals or health care providers of ordinary skill, care and diligence do - or not do - under similar conditions and circumstances in the delivery of plasmapheresis. Soehnlen focuses on the plasmapheresis treatments as the cause of her Hepatitis C infection and Dr. Rozman opined in his affidavit that: 1) a hospital has a duty to provide sanitary conditions, 2) a patient will not be exposed to Hepatitis C if sanitary conditions are maintained, and 3) plaintiff's Hepatitis C infection "necessarily resulted" from unsanitary medical equipment, including the plasmapheresis treatments, which she received from unsanitary medical personnel during her Aultman admission.

Although Dr. Rozman offers the conclusory opinion that plaintiff's plasmapheresis treatments were unsanitary, Dr. Rozman testified at his deposition that he did not know what the standard of care is for the administration of plasmapheresis, or the "specifics" of the practice, routine, or safety measures for protecting patients and personnel in the delivery of plasmapheresis. Plaintiff points to the deposition testimony of the nurses who administered the plasmapheresis treatments as evidence of unsanitary conditions. These nurses testified variously that they themselves did not perform certain general maintenance cleaning procedures contained in the operator's manual for the plasmapheresis unit,[47] and regarding their use and non-use of gloves when handling tubing, touching the plasmapheresis unit, and touching the patient during

[47] Judith Kramer Depo., pp. 23-27; Teresa Herzog Depo., pp. 19-21; Cindy Ickes Depo., pp. 37-39; Lisa Gallagher Depo., pp. 34-37.

the administration of plasmapheresis,[48] and regarding the use of plastic tubing for plasmapheresis that was several weeks beyond the expiration date on the package.[49]

However, Dr. Rozman's bare conclusion that the nurses' practices were "unsanitary" provides no information regarding what the standard of care is in the medical community for the administration of plasmapheresis regarding general maintenance cleaning, and glove and tubing use. Dr. Davenport, who has expertise in plasmapheresis, reviewed plaintiff's Aultman admission records and the nurses' depositions, and concluded:

> "There is no evidence of abnormal events, device alarms, or deviations from accepted medical practice in plasmapheresis. The depositions of the operators indicate that standard body substance precautions were used.
>
> . . . . . .
>
> There is no evidence that any breach of the standard of care occurred in Ms. Soehlen's [sic] plasmpheresis treatments."[50]

Even assuming for the moment that plaintiff established the standard of care and that the nurses' practices fell below the standard of care, plaintiff has not established that infection would not have occurred under the circumstance if ordinary care had been observed. For example, two nurses testified that tubing which had an expiration date of February 1, 2005, was used in plaintiff's plasmapheresis treatments during the last two weeks of March 2005.[51] Nurse Teresa Herzog testified in her deposition that she was instructed not to use expired tubing. Plaintiff's

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[48] Judith Kramer Depo., pp. 12-13, 30; Lisa Gallagher Depo., pp. 25-26.

[49] Judy Kramer Depo., p. 10; Cindy Ickes Depo., pp. 62-63.

[50] Dr. Davenport Report, p. 1-2.

[51] Judy Kramer Depo., p. 10; Cindy Ickes Depo., pp.62-63.

counsel asked Nurse Herzog if the reason for not using expired tubing was that it could leak or crack, but the witness was unsure.[52]

However, it is undisputed that there is no evidence that any leaks or breaks occurred during plaintiff's plasmapheresis treatments,[53] and plaintiff does not dispute Dr. Davenport's report that although a break in the system is rare, if it occurs it is "obvious to the operator" and "the blood is under pressure so that blood comes out and nothing can go in."[54] Plaintiff also does not dispute the statement of Nurse Wanda Salinas, who is responsible for training Aultman nurses in the administration of plasmapheresis, that "[i]f there are any breaks in the closed system during plasmpaheresis or any other deviations from the routine suggesting that sterility was not maintained, the system would require tear down and replacement," which would be documented.[55] Plaintiff has offered no evidence as to how use of this expired tubing would have exposed plaintiff to Hepatitis C or how her exposure would have been prevented if expired tubing had not been used. Plaintiff has similarly offered no expert explanation as to how the nurses' failure to clean the plasmapheresis machine's leak sensors in accordance with the manufacturer's instructions may have exposed plaintiff to Hepatitis C or how cleaning the sensors would have prevented an exposure.

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[52] Teresa Herzog Depo., p. 11.

[53] Dr. Davenport Report, p. 1-2.

[54] *Id.*

[55] Wanda Salinas Aff., Exhibit A.

The Court finds that even when the facts are viewed in the light most favorable to the non-moving party, plaintiff has not met her burden to establish the applicability of the evidentiary doctrine of *res ipsa loquitur* by showing that Aultman had exclusive control over the instrumentality causing her infection and that she would not have been exposed to Hepatitis C under the circumstances if the standard of care had been observed. Plaintiff argued for application of *res ipsa loquitur* because she admittedly cannot identify the specific negligent act which proximately caused her infection during her Aultman admission. Without the application of the doctrine to infer defendant's negligence, plaintiff cannot prove her medical negligence claim, and defendant is entitled to judgment as a matter of law.

IV. CONCLUSION

For the reasons discussed herein, the Court finds that when considering the facts in the light most favorable to the plaintiff there are no genuine issues of material fact from which a jury could reasonably find in favor of plaintiff. Accordingly, defendant's motion for summary judgment on Kathryn Soehnlen's negligence claim is granted (Document 121).[56] Although not part of Aultman's summary judgment motion, Philip Soehnlen's claim for loss of consortium depends on the survival of Kathryn Soehnlen's claim.

Defendant's motion to strike Dr. Rozman's affidavit is denied because it does not directly contradict his deposition testimony (Document 125). Plaintiff's motion to strike

[56] As discussed, *supra*, defendant is granted judgment on plaintiff's allegation that Aultman was negligent in connection with the albumin used in her plasmapheresis treatments because plaintiff's expert opined that the albumin was not the source of plaintiff's Hepatitis C infection.

Dr. Friedman's letter for lack of authenticity is denied as moot (Document 127).[57] Plaintiff's motion to strike defendant's experts' opinions that Soehnlen may have been infected with Hepatitis C prior to her admission to Aultman is also denied as moot in view of the Court's assumption for the purpose of this analysis that plaintiff contracted Hepatitis C during her Aultman admission (Document 127).

IT IS SO ORDERED.

April 24, 2008
Date

S/ David D. Dowd, Jr.
David D. Dowd, Jr.
U.S. District Judge

[57] Even though plaintiff's motion to strike is denied as moot because defendant provided an affidavit from Dr. Friedman authenticating his letter to Dr. Matto, the Court did not consider in its analysis Dr. Friedman's view that plaintiff's Hepatitis C infection may have pre-dated her Aultman admission.